

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRUNO HOFMANN

v.

PHILIP LAUGHLIN, et al.

Civ. No. 04-10027-JLT

**LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS OF
DEFENDANTS ALBERT ERANI, PHILIP LAUGHLIN, DONNA LOPOLITO,
MICHAEL SABOLINSKI, ALAN TUCK AND HERBERT STEIN IN
SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT**

Jeffrey B. Rudman (BBO #433380)
Jonathan A. Shapiro (BBO #567838)
Peter J. Kolovos (BBO #632984)
Peter A. Spaeth (BBO #545202)
Eric D. Levin (BBO #639717)
Sherry Hartel Haus (BBO #663777)
Kimberly I. Friday (BBO #660544)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

*Attorneys for Albert Erani, Donna Abelli
Lopolito, Philip Laughlin, Michael Sabolinski,
and Alan Tuck*

Peter M. Saporoff (BBO #441740)
Breton T. Leone-Quick (BBO #655571)
Mintz, Levin, Cohn, Ferris, Glovsky & Popeo PC
One Financial Center
Boston, MA 02109
(617) 542-6000

Attorneys for Herbert Stein

Dated: April 18, 2007

Defendants Albert Erani, Donna Abelli Lopolito, Philip Laughlin, Michael Sabolinski, Alan Tuck and Herbert Stein (collectively, “defendants”) submit this summary statement of undisputed material facts in support of their Motion for Summary Judgment.

I. Apligraf

1. Organogenesis, Inc. (“Organogenesis”) was founded in 1985 as a tissue engineering company. It developed Apligraf, which is “a unique skin replacement therapy” for skin wounds. See Compl. ¶¶ 2, 22, 46, 54.

2. “Apligraf is the only mass-manufactured product containing living human cells” to be approved by the U.S. Food and Drug Administration (“FDA”). See Ex. 1 - Form 10-K for 1998, at 2; Compl. ¶¶ 22, 49. Apligraf has been recognized as a “revolutionary” product and a “major medical breakthrough.” Compl. ¶¶ 22, 49.

3. On June 20, 1999, Organogenesis issued a press release which announced that the FDA had approved Apligraf for the treatment of venous leg ulcers. See Compl. ¶ 93.

4. Between November 15, 1999 and February 7, 2002, the FDA also approved Apligraf for treatment of diabetic foot ulcers (which lead to amputations and a high mortality rate) and for Medicare reimbursement in all 50 states. See Compl. ¶¶ 93, 97, 137; Ex. 2 - Press Release dated June 20, 2000; Ex. 3 - CNBC Interview dated June 26, 2000, at 4.¹

II. License and Supply Agreement with Novartis

5. In 1996, Organogenesis entered into a License and Supply Agreement with Sandoz Pharma Ltd. (which later was acquired by Novartis Pharma AG) whereby Novartis received an exclusive license to sell Apligraf and assumed responsibility to market and distribute the product, and the companies shared the revenue from those sales. See Ex. 4 - License and Supply Agreement, Form 10-K for 1995 (Exhibit 10(v)).

¹ All exhibits cited in this statement are attached to the Affidavit of Peter J. Kolovos.

6. The License and Supply Agreement was amended in 2001. See Ex. 5 - Amendment V to License and Supply Agreement, Form 8-KA (Exhibit 10.1) dated April 24, 2001.

7. The original License and Supply Agreement and subsequent amendments were filed with the Securities and Exchange Commission (“SEC”) in March 1996 and April 2001. See Ex. 4 - License and Supply Agreement, Form 10-K for 1995 (Exhibit 10(v)); Ex. 5 - Amendment V to License and Supply Agreement, Form 8-KA (Exhibit 10.1) dated April 24, 2001.

8. Between 1999 and 2001, Novartis was one of the largest pharmaceutical companies in the world with revenue of \$21.7 billion and net income of \$4.5 billion in 1999, revenue of \$21.3 billion and net income of \$4.3 billion in 2000, and revenue of \$18.9 billion and \$4.2 billion in 2001. See Ex. 6 - Novartis AG Form 20-F for 2001.

III. Organogenesis’ Financial Statements

9. Every financial statement that Organogenesis filed with the SEC from 1998 through February 7, 2002 contained accurate financial information (including revenues, expenses, profits/losses, margins, and sales of Apligraf) and complied with Generally Accepted Accounting Principles (“GAAP”). See Exs. 7 - 16.

A. Disclosures of Chronic and Increasing Losses

10. In its SEC filings, Organogenesis disclosed its losses over a long historical period to its investors. For example, in its Form 10-K for 1998, Organogenesis disclosed that it had incurred net losses for every year since 1994, including a \$14 million net loss that year (1998), and further disclosed that “[w]e may incur additional losses as expenditures continue to increase due to expansion of operations and research programs. See Ex. 1 - Form 10-K for 1998 at 15, 18. In its 10-K for 1999, Organogenesis further disclosed that it had lost money in every year of its 15-year existence:

Organogenesis Inc. was founded in 1985. *We have incurred operating losses in every year of our existence.*

Ex. 10 - Form 10-K for 1999, at 83 (emphasis added); see also Ex.12 - Form 10-K for 2000, at 211 (same).

11. Organogenesis accurately reported the following net losses in its SEC filings from 1994 through the first quarter of 2002:

<u>Period</u>	<u>Net Loss</u>	<u>Source</u>
Fiscal year ended December 31, 1994	\$10.4 million loss	Ex. 1 - Form 10-K for 1998, at 15
Fiscal year ended December 31, 1995	\$12.7 million loss	Ex. 1 - Form 10-K for 1998, at 15
Fiscal year ended December 31, 1996	\$7.5 million loss	Ex. 1 - Form 10-K for 1998, at 15
Fiscal year ended December 31, 1997	\$19.8 million loss	Ex. 1 - Form 10-K for 1998, at 15
Fiscal year ended December 31, 1998	\$14.0 million loss	Ex. 1 - Form 10-K for 1998, at 15
Q3 1999	\$6.48 million loss	Ex. 7 - Form 10-Q for Q3 1999, at 4; Ex. 8 – Form 10-Q/A for Q3 1999, at 4.
Q4 1999	\$8.3 million loss	Ex. 9 - Press Release dated March 31, 2000
Fiscal year ended December 31, 1999	\$28.3 million loss	Ex. 10 - Form 10-K for 1999, at 15
Q1 2000	\$6.7 million loss	Ex. 11 - Form 10-Q for Q1 2000, at 4
Q2 2000	\$2.0 million loss	Ex. 12 - Form 10-Q for Q2 2000, at 4
Q3 2000	\$6.9 million loss	Ex. 13 - Form 10-Q for Q3 2000, at 4
Q4 2000	\$7.4 million loss	Ex. 14 - Form 10-K for 2000, at 43
Fiscal year ended December 31, 2000	\$28.6 million loss	Ex. 14 - Form 10-K for 2000, at 15
Q1 2001	\$6.5 million loss	Ex. 15 - Form 10-Q for Q1 2001, at 4
Q2 2001	\$8.6 million loss	Ex. 16 - Form 10-Q for Q2 2001, at 4
Q3 2001	\$7.5 million loss	Ex. 17 - Form 10-Q for Q3 2001,

		at 4
Q4 2001	\$7.5 million loss	Ex. 18 - Form 10-K for 2001, at 53
Fiscal year ended December 31, 2001	\$30.1 million loss	Ex. 18 - Form 10-K for 2001, at 21

12. In these SEC filings, Organogenesis disclosed aggregate net losses of \$41.3 million from 1996 to 1998, and aggregate net losses of \$87 million from 1999 to 2001, for a total of \$128.3 million in aggregate losses for the five-year period from 1996 to 2001. See Exs. 1, 10, 14, 18 - Form 10-Ks for 1998, 1999, 2000, 2001.

13. The Company's annual losses increased with each successive year in 1998, 1999, 2000, and 2001. See id. (\$14.0 million loss in 1998; \$28.3 million loss in 1999; \$28.6 million loss in 2000; \$30.1 million loss in 2001).

B. Disclosures of Revenues, Sales of Apligraf, and Margins

14. Organogenesis accurately disclosed the following sales of Apligraf in its press releases from the third quarter of 1998 through the first quarter of 2002:

<u>Quarter</u>	<u>Apligraf Sales - Units</u>
Q3 1998	548 units
Q4 1998	1,070 units
Q1 1999	1,585 units
Q2 1999	1,755 units
Q3 1999	1,817 units
Q4 1999	2,192 units
Q1 2000	2,555 units
Q2 2000	2,814 units
Q3 2000	3,232 units
Q4 2000	4,084 units
Q1 2001	5,194 units
Q2 2001	5,244 units
Q3 2001	6,606 units
Q4 2001	6,822 units
Q1 2002	7,102 units

See Ex. 19 - Press Release dated April 16, 1999; Ex. 20 - Press Release dated August 2, 2001; Ex. 21 - Press Release dated October 4, 2001; and Ex. 22 - Press Release dated April 3, 2002.

15. Unit sales of Apligraf increased by 220% between Q3 1998 and Q2 1999 (from 548 units/quarter to 1,755 units/quarter), and by almost 400% from Q3 1999 through Q1 2002 (from 1,817 units/quarter to 7,102 units/quarter). See id.

16. Unit sales of Apligraf improved in every quarter from Q3 1998 through Q1 2002. See id.

17. Revenues from product sales increased from \$42,000 in 1996 to \$1,189,000 in 1998, an increase of 2,731%. See Ex. 1 – Form 10-K for 1998, at 17. Revenues from product sales further increased to \$1,844,000 in 1999, and continued to increase to \$8,191,000 in 2001, an additional increase of 344% between 1999 and 2001. See Ex. 18 - Form 10-K for 2001, at 24.

18. Organogenesis' public filings demonstrate that its gross profit margins improved from the first quarter to the second quarter in the year 2000. Gross profit margin for Q1 2000 was as follows:

$$\frac{[\text{product sales} - \text{cost of product sales}]}{\text{cost of product sales}} = \frac{646,000 - 1,191,000}{1,191,000} = -45.8\% \text{ (rounded)}$$

Gross profit margin for Q2 2000 was as follows:

$$\frac{[\text{product sales} - \text{cost of product sales}]}{\text{cost of product sales}} = \frac{719,000 - 1,310,000}{1,310,000} = -45.1\% \text{ (rounded)}$$

Ex. 11 – Form 10-Q for Q1 2001, at 11; Ex. 12 – Form 10-Q for Q2 2001, at 11.

IV. Disclosures Regarding Liquidity and Need for Financing

19. Organogenesis expressly warned investors in its Form 10-K for 1999 that it expected to continue to incur losses and might never become profitable:

OUR COMPANY HAS A HISTORY OF LOSSES AND WE EXPECT TO CONTINUE TO INCUR LOSSES

We have not achieved profitability and *expect to continue to incur net losses*. The extent of future losses and the time required to achieve profitability is highly uncertain.

Ex. 10 - Form 10-K for 1999, at 5 (emphasis added).

20. In its Form 10-K for 2000, Organogenesis told investors that it “expect[ed] to continue to incur net losses through at least the first half of 2002.” Ex. 14 - Form 10-K for 2000, at 5.

21. The Company warned investors that it would have to curtail or even cease operations if it could not raise additional financing to fund operations, and that such additional funds might not be available:

Additional funds may not be available when required on acceptable terms. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs . . . resulting in potential material adverse effect on our financial condition and results of operations.

Ex. 1 - Form 10-K for 1998, at 20; see also Ex. 10 – Form 10-K for 1999, at 22 (similar); Ex. 14 - Form 10-K for 2000, at 217 (similar).

22. Organogenesis also told investors that “production costs” exceeded “product sales” for Apligraf. Ex. 7 – Form 10-Q for Q3 1999; Ex. 8 - Amended Form 10-Q for Q3 1999.

V. Disclosures Regarding the Manufacturing and Marketing of Apligraf

23. Organogenesis warned investors that problems could arise with the manufacturing of Apligraf because the manufacturing process was complex and that any problems could adversely affect its operations:

The process of manufacturing our products is *complex* . . . with increasing demand for Apligraf, we must further transition from small-scale to full-scale production of our products. If we do not make the full transition successfully, we will not be able to satisfy the demands for our products and our results of operations will be hurt.

Ex. 1 - Form 10-K for 1998, at 10 (emphasis added).

24. As of 2001, Apligraf was being produced at a rate of more than 40,000 units per year. See Compl. ¶ 136.

25. Organogenesis warned investors that Novartis might not be successful in marketing Apligraf in its Form 10-K for 1998:

[O]ur collaborators might not be successful in gaining market acceptance for our products We are dependent on Novartis for the successful marketing and selling of Apligraf worldwide. If Novartis does not succeed in marketing and selling Apligraf . . . our operating results will suffer.

Ex. 1 - Form 10-K for 1998, at 11.

26. Organogenesis also warned investors that Novartis might not be successful in marketing Apligraf in its Form 10-K for 2000:

We are dependent on Novartis for the successful marketing and selling of Apligraf worldwide. If Novartis does not succeed in marketing and selling Apligraf or gaining international approvals for the product or if we are unable to meet the production demand of global commercialization, our operating results will suffer..

Ex. 10 - Form 10-K for 1999, at 6.

27. Prior to Apligraf, no one had ever marketed or sold a living-tissue product. See Compl. ¶¶ 2, 54, 146.

VI. Facts Showing that Alleged Fraud Did Not Cause Any Loss

28. On January 30, 2002, the Company announced that it was running out of money and would cease operations if it could not obtain new financing. See Compl. ¶ 148.

29. Below is a summary of the behavior of Organogenesis' stock price in the days before and immediately after this announcement:

- On January 24, 2002 (Thursday), Organogenesis' stock price closed at \$3.85.
- The next day on January 25, 2002 (Friday), Organogenesis' stock price dropped to close at \$3.53, a *decrease* of 8.31% from the prior day. There was no news announced on this day.
- On the next business day – January 28, 2002 (Monday) – Organogenesis' stock price again dropped to close at \$3.09, a *decrease* of 12.46% from the prior business day. Once again, there was no news announced on this day.

- On January 29, 2002 (Tuesday) – the day *before* the supposed revelation of the “truth,” see Compl. ¶¶ 14, 148-51 – Organogenesis’ stock price once again dropped to close at \$2.35, a total *decrease* of 23.95% from the prior day. The only news announced on this day was the promotion of Steven Bernitz to Executive Vice President and Chief Operating Officer. See Ex. 23 - Press Release dated Jan. 29, 2002. This news had no connection to the fraud alleged in the Complaint.
- Thus, from January 24 to 29, 2002, Organogenesis’ stock price fell from \$3.85 to \$2.35, a *decrease* of 39%, and the only news announced during these days had nothing to do with the alleged fraud.
- By contrast, on January 30, 2002 (Wednesday), the day the alleged fraud was supposedly revealed, Organogenesis’ stock price closed at \$2.66, an *increase* of \$.31 or 13.19% from the prior day. The announcement on Form 8-K that plaintiffs contend revealed the truth of defendants’ alleged scheme to defraud the market was released at 3:38 p.m., 22 minutes before the close of trading. See Ex. 24 – Form 8-K filed January 30, 2002.
- On January 31, 2002 (Thursday) – the day after the supposed fraud was revealed – Organogenesis’ stock price closed at \$2.60, a decrease of *only* \$.06 or 2.26% from the prior day.²

² Organogenesis’ closing stock prices for January 4, 1999 through September 15, 2003 are set forth in Exhibit 25, as reported by Sungard (formerly Tradeline) and published by LEXIS.

Respectfully Submitted,

ALBERT ERANI, PHILIP LAUGHLIN, DONNA
ABELLI LOPOLITO, MICHAEL SABOLINSKI,
and ALAN W. TUCK

By their attorneys,

/s/ Eric D. Levin

Jeffrey B. Rudman (BBO #433380)
Jonathan A. Shapiro (BBO #567838)
Peter A. Spaeth (BBO #545202)
Eric D. Levin (BBO #639717)
Sherry Hartel Haus (BBO #663777)
Kimberly I. Friday (BBO #660544)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

HERBERT STEIN

By his attorneys,

/s/ Peter M. Saporoff

Peter M. Saporoff (BBO #441740)
Breton T. Leone-Quick (BBO #655571)
Mintz, Levin, Cohn, Ferris, Glovsky & Popeo PC
One Financial Center
Boston, MA 02109
(617) 542-6000

Dated: April 18, 2007

CERTIFICATE OF SERVICE

I hereby certify that a true copy of this document was filed through the ECF system on April 18, 2007, and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Eric D. Levin

Eric D. Levin